

REMARKS/ARGUMENTS

Prior to calculation of any filing fees and examination, the entry of this amendment is respectfully requested.

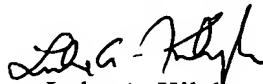
The Preliminary Amendment cancels claims 1-13 and adds new claims 14-35. The applicants wish to point out to the Examiner that new claims 14-35 correspond to claims 27-48 which were set forth in Parent Application No. 09/914,552. In the Parent Application and in particular in the Office Action dated November 12, 2003 in the Parent Application, the Examiner applied a restriction requirement and concluded that these claims are directed to kit claims and therefore are directed to a separate and distinct invention from the method claims. The applicants do wish to point out that the Examiner indicated that the Parent Application was not filed under §371 as a National Stage application and therefore U.S. restriction practice applies. However, the Examiner is incorrect. By viewing the filing receipt as well as the filing papers, it is clear that the Parent Application is a §371 National Stage entry of a PCT application. The Examiner is respectfully requested to make note of this point with respect to future examination and restriction practices.

Support for the amendment can be found in the present application as indicated in the Amendment filed August 25, 2003 in the Parent Application. Accordingly, no questions of new matter should arise, and entry of this amendment is respectfully requested.

If there are any fees due in connection with the filing of this Preliminary Amendment, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Preliminary Amendment
U.S. Patent Application No. Unassigned

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Luke A. Kilyk', is written over the printed name.

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CLAIMS

1. (After amendment) A method for assaying a specific component
in a lipoprotein fraction in a serum by an enzymatic reaction, which
5 comprises introducing a controlling means which is established by
selecting the enzymatic reaction, for enabling an enzymatic reaction
preferentially with respect to an object component in the specific
lipoprotein fraction without forming complexes nor aggregates,
thereby specifically assaying the component.
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2. A method for assaying a specific component in a lipoprotein
fraction according to claim 1, wherein said controlling means is
a means for controlling ion strength of a reaction liquor so as
to facilitate the enzymatic reaction of the target component in
15 the specific lipoprotein fraction in the reaction liquor.
3. A method for assaying a specific component in a lipoprotein
fraction according to claim 2, wherein said controlling ion strength
increases the ion strength of the reaction liquor to a sufficiently
20 high level so as to facilitate the enzymatic reaction of the component
in a high-density lipoprotein (HDL) in the liquor.
4. A method for assaying a specific component in a lipoprotein
fraction according to claim 1, wherein said controlling means is
25 a means for enabling the enzymatic reaction directly and/or
preferentially with respect to the component in the specific

lipoprotein fraction in the reaction liquor, utilizing reaction specificity of an enzyme to the specific lipoprotein.

5. A method for assaying a specific component in a lipoprotein
5 fraction according to claim 4, wherein said means for enabling the enzymatic reaction directly and/or preferentially with respect to the component in the specific lipoprotein fraction is reacting lipoprotein lipase and/or cholesterol esterase that preferentially act(s) on the HDL fraction.

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6. A method for assaying a specific component in a lipoprotein
fraction according to claim 1, wherein said controlling means is a means for enabling the enzymatic reaction directly and/or preferentially with respect to the component in the specific
15 lipoprotein fraction in the reaction liquor, utilizing reaction selectivity of a selected nonionic surfactant to the specific lipoprotein.

7. A method for assaying a specific component in a lipoprotein
20 fraction according to claim 1, wherein a nonionic surfactant that has reaction selectivity to the HDL fraction and an HLB value of 16 or more is used as said nonionic surfactant, thereby enabling the enzymatic reaction directly and/or preferentially with respect to the component in the HDL fraction in the reaction solution.

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8. The method for assaying a specific component in a lipoprotein

fraction according to claim 1, wherein said assaying method according to claim 5 and said assaying method(s) according to claims 3 and/or 7 are carried out in combination.

5 9. The method for assaying a specific component in a lipoprotein fraction according to claim 1, wherein said assaying method(s) according to claim 4 and said assaying method according to claims 2 and/or 6 are carried out in combination.

10 10. The method for assaying a specific component in a lipoprotein fraction according to claim 1, wherein said method is a method for assaying cholesterol in an LDL fraction, which comprises introducing a means for selectively subjecting a cholesterol component in an HDL fraction to an enzymatic reaction to assay or digest thereof
15 in the first enzymatic reaction system utilizing said assaying method according to claim 8 or 9, and then subjecting the cholesterol component in the LDL fraction to an enzymatic reaction in a second enzymatic reaction system by utilizing said assaying method according to claim 4 and a nonionic surfactant that has an HLB value
20 of 11 to 13.

11. The method for assaying a specific component in a lipoprotein fraction according to claim 1, wherein said method is a method for assaying cholesterol in a VLDL (very low-density lipoprotein)
25 fraction, which comprises simultaneously or separately treating said first enzymatic reaction system and said second enzymatic

reaction system in said assaying method according to claim 10 to have the cholesterol component remained and then introducing a means for decomposing the VLDL fraction to subject the cholesterol component in the VLDL fraction to an enzymatic reaction.

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12. The method for assaying a specific component in a lipoprotein fraction according to any one of claims 8 to 11, further comprising a step for adding cholesterol oxidase or cholesterol dehydrogenase to digest free cholesterol.

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13. The method for assaying a specific component in a lipoprotein fraction according to any one of claims 1 to 12, wherein pH of the reaction solution is selected from within a range where the lipoprotein does not form aggregates nor make the reaction solution
15 cloudy and in view of an optimal pH of an enzyme used in the enzymatic reaction of the component in the lipoprotein.